JAY INSLEE
Governor

STATE OF WASHINGTON
Office of the Governor

August 16, 2018

The Honorable Andrew Wheeler
Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Dear Acting Administrator Wheeler:

Several Washington state agencies charged with protecting human health and the environment have recently commented on your agency's proposed rule known as the "transparency" rule (Strengthening Transparency in Regulatory Science - Docket ID No. EPA-HQ-OA-2018-0259). I am writing in support of those comments and the request to withdraw the rule.

I find your rule to be a solution in search of a problem. Since its creation, the U.S. Environmental Protection Agency (EPA) has used science for the betterment of the country in ways that are indisputable. Starting with the successful implementation of the Clean Air Act that eliminated the problem of acid rain and checked the choking impacts of smog in our cities, scientific rigor has been the bedrock for action. Turning peer-reviewed academic research into comprehensive assessments often followed by advisory panel review and ultimately an open, public rule-making is a long and painstaking process. Despite the slow development of even the most obvious of scientific findings into positive action, I have supported the rigor of this process that allows for detailed scrutiny from all stakeholders.

The proposed rule cites the need for increased transparency but provides little evidence that this need is not being met. EPA models, for example, that serve as the basis for predicting cancer risk and blood lead levels in children are well presented, explained and supported. It is quite true that debate continues on the accuracy of such models but there is little debate that they are transparent. It appears that the only thing left for more transparency is the raw data itself, an approach that dismisses the value of the peer-review process. Setting aside the unsupported cynicism that such an attitude implies toward peer-review as a foundational piece of the scientific process, the ramifications of requiring raw data beyond what is in the peer-reviewed literature are unacceptable.

Disclosure of human data from epidemiology studies violates the integrity of that hugely important tool necessary for the protection of human health. Participants are rightly guaranteed confidentiality when they participate in such studies. Epidemiology should be welcomed by those who question modeling, often based on animal studies, as it looks at the impacts of real

world exposure in the very people that regulations are designed to protect. Redacting personal information as a solution proposed by the previous administrator shows a lack of understanding and appreciation for how these studies are approved and executed. Simply stated, risking the future use of the critical public health tool that is epidemiology is a fool's errand.

I also must question the intent here. The agency shows little stomach for increasing transparency for the thousands of chemicals in the millions of products we buy everyday citing the need for business to keep trade secrets confidential. A legitimate concern but with valid solutions. I find it hypocritical for the administration to push for unsubstantiated and unnecessary increases in transparency that could threaten public health while failing to share information on toxics in products with states.

Finally, more and more we find that science has become a political target attacked not because of its substance but because of who is delivering it or what it might mean to our way of life. These attacks are not rooted in the necessary skepticism of scientific inquiry but instead are born of a distaste for the answer itself. Sir Austin Bradford Hill, who is credited with drawing the link between smoking and cancer, famously wrote in his seminal paper on biostatistics that:

"All scientific work is incomplete - whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time."

I hope that you will reconsider the detrimental effect that your proposed rule could have on advancing science so that we continue to heed new science while rejecting the easy temptation to hide behind the uncertainty that inevitably comes with it.

Very truly yours,

Jay Inslee
Governor

Enclosures

DEPARTMENT OF ECOLOGY State of Washington

Washington Department of FISH and WILDLIFE

WASHINGTON STATE DEPT OF NATURAL RESOURCES HILARY S. FRANZ COMMISSIONER OF PUBLIC LANDS

WASHINGTON STATE Recreation and Conservation Office

August 15, 2018

The Honorable Andrew Wheeler, Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Mail Code: 28221T
Washington, DC 20460

Re: Strengthening Transparency in Regulatory Science (Docket ID No. EPA-HQ-OA-2018-0259)

Dear Administrator Wheeler:

The Washington State Departments of Ecology, Fish and Wildlife, Natural Resources, and the Recreation and Conservation Office, respectfully submit comments on the proposed rule Strengthening Transparency in Regulatory Science (40 CFR Part 30).

We urge the U.S. Environmental Protection Agency (EPA) to withdraw the proposed rule for the following reasons:

- The proposed rule lacks detail and EPA has provided no supporting information to justify why the rule is beneficial. EPA did not evaluate the costs and benefits of the rule or provide any information on rule implementation.

- We have significant concerns that the proposed rule would impede EPA's ability to use established, peer-reviewed scientific evidence to set standards that protect the health of Washington State citizens and our environment.

- The proposed rule would hinder important research by requiring EPA only consider scientific studies where the underlying data, models, and methodologies are made publicly available and sufficient for independent validation. We have deep concerns about EPA's ability to implement the rule in a manner that allows the use of the best scientific information, while ensuring scientific progress and adequately protecting patient, business, and citizen privacy.

Thank you for the opportunity to provide our perspective on this important issue.

Maia D. Bellon, Director
Washington State Department of Ecology

Kelly Susewind, Director
Washington Department of Fish and Wildlife

Hilary S. Franz, Commissioner of Public Lands
Washington Department of Natural Resources

Kaleen Cottingham, Director
Washington State Recreation and Conservation Office

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Comments

I. Introduction

We have significant concerns that the proposed rule would impede EPA's ability to use established, peer-reviewed scientific evidence to set standards that protect the health of the citizens of Washington State and our environment, and urge EPA to withdraw the proposed rule. We appreciate EPA's decision to extend the public comment period and hold a public hearing to allow states, researchers, and other interested parties sufficient time to evaluate and comment on the proposed rule.

The proposed rule would require that EPA only consider scientific studies where the underlying data, models, and methodologies are made publicly available and sufficient for independent validation. Dose-response data and models involving human subjects are the gold standard for assessment of direct human health effects. These studies typically rely on patient data that is protected by the Health Insurance Portability and Accountability Act (HIPPA) law that safeguards and protects privacy of personal patient medical information. Further, environmental studies often require sensitive information about private citizens, companies and private properties. Federal and state agencies and academic institutions have robust processes in place and human subjects review boards to safeguard confidential information and meet high ethical standards. As long as these studies meet appropriate standards for data quality and scientific peer review they should be an integral part of the setting of environmental standards.

We have deep concerns about EPA's ability to implement the rule in a manner which allows the use of the best scientific information, while ensuring scientific progress and adequately protecting patient privacy. It is unclear how research efforts will be hindered by the requirement that de-identified health data on individual study subject be shared publically. For example, the U.S. Department of Health and Human Services *Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule*[1] Safe Harbor method requires deletion of all geographic subdivisions smaller than a state in order to de-identify healthcare data. This information loss would render analysis of spatial variability of health information in air pollution epidemiology research impossible.

II. The current process is adequate

The EPA currently uses robust, transparent processes to evaluate the best available scientific research, characterize the health hazards of chemicals and air pollution, and set standards to protect public health and the environment. It is a standard practice for EPA to conduct comprehensive reviews of the best available scientific research when evaluating air and water quality standards. EPA relies on peer-

[1] U.S. Department of Health and Human Services, Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Ace (HIPAA) Privacy Rule, https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html.

reviewed studies that describe the underlying data, methods, assumptions, sensitivity, and uncertainty of the results. These studies are cited and are published and available for public review. Reproducibility and independent validation are critical aspects of the scientific method, and have resulted in significant advancements in our understanding of the health effects of air pollutants at different exposures and thresholds.

EPA relies on independent advisory panels comprised of nationally-recognized experts, such as the Scientific Advisory Board (SAB), and the Clean Air Scientific Advisory Committee (CASAC), to review and evaluate the state of the research and to provide an additional layer of independent peer-review. EPA has existing policies and procedures in place to prevent conflicts of interest and ensure that the boards and committees are well-balanced, and comprised of independent members with the appropriate expertise. The processes for developing human health assessment and setting and reviewing standards by EPA have been routinely scrutinized by organizations such as the National Academy of Sciences (NAS) and the Government Accountability Office (GAO). EPA has incorporated their recommendations and improved its approach over time.[2]

Several of the landmark studies on the health effects of air pollution, such as the Harvard Six Cities and American Cancer Society studies, have been peer-reviewed and re-analyzed by multi-disciplinary expert panels from the Health Effects Institute (HEI).[3] HEI is an independent non-profit research institute that receives funding from both EPA and industry to provide impartial credible science on the health effects of air pollution. In testimony before a Congressional committee, the President of HEI stated that "US EPA and other agencies have established procedures to produce and review science for decisions, and in many cases those procedures work to enhance the quality and credibility of the science."

The proposed rule uses the phrase "*best available science*", but calls into question established processes such as EPA's integrated risk assessment system (IRIS) review program and National Ambient Air Quality Standards (NAAQS) program. In fact, EPA routinely makes the 'best' use of scientific information in these programs. That includes study-by-study evaluation of strengths and weaknesses of all relevant research. Also EPA more-than-adequately explains its decisions and analyses both in recommending NAAQS revisions and in quantifying chemical toxicities in IRIS.

IRIS is not a regulatory program, but it provides essential scientific information for decisions made by Washington State Department of Ecology. In a recent review of the IRIS program, the National Academy of Sciences reported that EPA has made "substantial progress" in implementing the recommendations outlined in previous NAS reports, improving the program's overall scientific and technical performance.[4]

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[2] See for example National Academy of Sciences (NAS), 2018, Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation, https://www.nap.edu/catalog/25086/progress-toward-transforming-the-integrated-risk-information-system-iris-program; National Research Council, 2000, Strengthening Science at the U.S. Environmental Protection Agency: Research Management and Peer-Review Practices, https://www.ncbi.nlm.nih.gov/books/NBK225708/.

[3] See Health Effects Institute, 2000, Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality, https://www.healtheffects.org/publication/reanalysis-harvard-six-cities-study-and-american-cancer-society-study-particulate-air.

[4] National Academy of Science, April 11, 2018, EPA's IRIS program has made substantial progress, says new report, http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=25086.

IRIS uses a rational weight-of-evidence method to assess available research, and provide access to a comprehensive source of toxicity data. It increases our capacity to evaluate chemical hazards, and to quantify risk magnitudes and uncertainties, but it does not tell us how to manage risks. The proposed exclusion of research lacking all underlying data from IRIS would be an unnecessary waste of information.

The NAAQS review process is a model of scientific transparency. Its reviews are renowned for their high quality. In regard to the studies on which they are based, the costs of publication as well as requirements for the privacy of study subjects have prohibited making all the data obtained publically available. We strongly disagree that this diminishes the value of such epidemiology and toxicology studies to regulatory science. Exclusion of such studies would significantly reduce the amount of scientific data available to establish appropriate standards to protect public health and the environment.

The proposed rule offers very little in the way of examples of non-transparent science. Instead it asserts "[a]*s a case in point, there is growing empirical evidence of non-linearity in the concentration-response function for specific pollutants and health effects*". That is true, however it has nothing to do with lack of public access of underlying research data. Instead, it calls for increased federal funding of research on non-linearity of pollution health impacts.

III. Recent actions by EPA undermine independent, scientific research

We have concerns that this proposed rule, and other recent actions by EPA will undermine scientifically robust, well established, existing processes. For example, EPA announced in 2017 that it would prohibit participation in CASAC of scientists from leading research institutions that receive EPA research grants.[5] EPA filled a number of the vacancies with researchers funded by the industries that EPA is responsible for regulating.[6]

EPA has also reduced or eliminated funding for critical scientific research programs such as the Science to Achieve Results (STAR) grants.[7] EPA should focus its efforts on improving existing processes and restoring funding for scientific research rather than establishing arbitrary, costly requirements that would further delay and diminish environmental research and potentially delay or weaken health-based standards.

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[5] U.S. EPA, Oct. 31, 2017, Administrator Pruitt Issues Directive to Ensure Independence, Geographic Diversity & Integrity in EPA Science Committees, https://www.epa.gov/newsreleases/administrator-pruitt-issues-directive-ensure-independence-geographic-diversity.

[6] See *Science*, Nov. 3, 2017, EPA unveils new industry-friendlier science advisory boards, http://www.sciencemag.org/news/2017/11/epa-unveils-new-industry-friendlier-science-advisory-boards.

[7] See U.S. EPA, 2018, FY 2019 Budget in Brief, https://www.epa.gov/sites/production/files/2018-02/documents/fy-2019-epa-bib.pdf

IV. The proposed rule would weaken our ability to protect public health and environment

We are concerned that the proposed rule would limit scientific research available for setting air quality standards to protect public health, and that EPA could use this rule to justify delaying new or weakening existing standards that protect the most vulnerable citizens from adverse health effects. The State of Washington relies on the scientific research and standards set by EPA to protect the health of our citizens and the environment.

Children are at greater risk from air pollution because they are physically developing and because they have higher inhalation rates than adults do. We disagree with part IV. Statutory and Executive Orders Reviews, section H. of the proposed rule. The claim that this action "is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk" to children is not supported by scientific evidence. In fact, there is substantial body of research showing children are more sensitive than adults to environmental pollution.

We also disagree with part IV, section K., which claims that this action is not subject to Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations. According to EPA, the purpose of Executive Order 12898 is to "focus federal attention on the environmental and human health effects of federal actions on minority and low-income populations with the goal of achieving environmental protection for all communities."[8] There is a large and growing body of evidence that minority and low-income populations face greater exposures to environmental pollution and are more susceptible to its effects. Efforts to delay or weaken air quality standards would disproportionately impact these communities. We urge EPA to consider the environmental justice implications of the rule and examine ways to further protect vulnerable people and disadvantaged communities, in accordance with Executive Order 12898.

The last sentence in section II of the preamble to the proposed rule says "The Agency's offices should be guided by this policy to the maximum extent practicable during ongoing regulatory action, even where such research has already been generated, solicited, or obtained." Previously published studies that followed Institutional Review Board protocols to protect participant privacy could not retroactively release their underlying data because to do so would be a gross violation of both ethical norms and institutional rules. Many of these studies are the bedrock of our understanding of human health effects of air pollution exposure.

Exclusion of existing research reports from regulatory actions just because the reports do not present all their underlying data would be a huge and unnecessary waste of information and the funding used to develop it. We urge EPA to focus their efforts on future improvements rather than undertaking a costly, process to vet and review the comprehensive body of knowledge on the health hazards of air pollution.

[8] U.S. EPA, Summary of Executive Order 12898 – Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, https://www.epa.gov/laws-regulations/summary-executive-order-12898-federal-actions-address-environmental-justice.

V. Procedural concerns

The proposed rule is lacking in detail and EPA has not provided any supporting information to justify why the rule is beneficial. Moreover, EPA has not fully evaluated the costs and benefits of the rule. The costs of the rule could be significant, especially if EPA decides to apply the rule retrospectively, and use the rule as a tool to revise existing health-based air quality standards. We urge EPA to provide additional clarification on the proposal, including evaluating the costs and benefits, and clarifying how the rule would be implemented. EPA should also evaluate what data would be available for setting health-based air quality standards if the rule was applied retroactively and prospectively, and consider how it would impact EPA's ability to protect public health and the environment.

VI. Recommended revisions to Part 30 - Transparency in Regulatory Decision Making

§ 30.6 Additional requirements pertaining to the use of dose response data and models underlying pivotal regulatory science.

We agree with the first sentence of this section (*"EPA shall describe and document any assumptions and methods used, and should describe variability and uncertainty."*), and if a rule is finalized we would find this language acceptable. However, the remainder of the language in this section, if still desired after further evaluation, would be better placed in policy or guidance documents.

VII. Conclusion

In summary, we request that EPA withdraw the proposed rule. We recommend that EPA work with states, research institutions, and organizations such as the National Academy of Sciences to identify improvements to existing processes designed to increase transparency and advance scientific research.

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

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August 16, 2018

The Honorable Andrew Wheeler
Administrator
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Administrator Wheeler:

Re: Strengthening Transparency in Regulatory Science, Docket ID No. EPA-HQ-OA-2018-0259

The Washington State Department of Health (DOH) writes to express our serious concerns with the proposed rule, "Strengthening Transparency in Regulatory Science," printed in the Federal Register on June 25, 2018 (83 Fed. Reg. 24255). We urge you to withdraw this rule because it will compromise the protection of public health by reducing the amount of credible science available for decision making.

The rule proposes unreasonable procedural barriers to environmental public health scientific inquiry and policy development and limits the scope of scientific information available to inform policy. For example, published epidemiological information about changing hospital admissions for respiratory illness before, during and after the shutdown of a steel mill (Pope, 1989) appears to be excluded from consideration because this sort of "natural experiment" is not practicably reproducible. In other cases, the original studies cannot be replicated because the exposure conditions no longer exist, thanks to regulation. Since the rule is retroactive it may overturn existing policies that are based on studies where the original raw data is no longer accessible or must be withheld to comply with ethical and legal requirements of epidemiological research (e.g., requirements of an Institutional Review Boards and/ or the Health Insurance Portability and Accountability Act of 1996 (HIPAA)). By disqualifying high quality longitudinal epidemiological and clinical studies - often the most direct and relevant evidence of chemical impacts on humans - the proposed rule would diminish not strengthen the science underlying regulations.

In addition, the proposed rule establishes increased protections for confidential business information, diminishing the amount of information available to the public to inform policy, whether from the scientific community or from the business community. These provisions reduce rather than increase public transparency.

The Washington State Department of Health depends on the EPA for timely scientific research, assessments and policy to inform our efforts to protect our residents from environmental hazards, such as those associated with contamination of drinking water with perfluorinated compounds (PFAS). The added administrative barriers resulting from this rule are likely to significantly delay the development of EPA guidelines and policies. Such delays and the resulting reduced health protection are expected due to decreased access to industry claimed confidential business information, exclusion of relevant peer

reviewed scientific studies, and the need for researchers to prepare publically disclosable datasets. Such delays will result in prolonged public exposure to environmental hazards, increased costs to researchers, and increased societal costs due to unmitigated harm to the environment and to the health of our population.

In the background section of this proposed rule, the cost of compliance with "significant regulations" is provided as justification for the proposed rule. Subsequently, it is suggested that dose response modeling used by EPA scientists for "pivotal regulatory science" is overly protective of health and the environment and therefore places unnecessary regulatory and financial burdens on industry. This justification for the proposed rule does not account for the short and long-term costs to individuals and communities from environmental degradation and the resulting population health impacts. The comprehensive dose response modelling that takes into account all available peer reviewed scientific studies provides reasonable though imperfect protection. Increasingly and across a wide range of chemicals and exposure pathways, we are learning about adverse environmental and public health effects from exposure levels much lower than ones previously thought to be safe. Approximately 13 percent of the total burden of disease in the United States has been attributed to environmental exposures. These diseases contribute to more than 398,000 deaths annually (Pugh & Gregory, 2012). Refinement of EPA dose-response models would likely improve public health. This refinement would be more likely accomplished by *increased* disclosure of confidential business information, not by the increased protection of confidential business information and decreased availability of scientific information.

In section IV, Statutory and Executive Orders Reviews, it is stated that this proposed rule does not have implications relevant to Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments). This assertion does not seem to be adequately supported, and we urge additional analysis of the probable impacts of the proposed rule on Tribal Nations.

We disagree with part IV, Statutory and Executive Orders Reviews, section H, of the proposed rule. The claim that this action "is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk" to children is not supported by scientific evidence. In fact, there is a substantial body of research showing children are more sensitive than adults to environmental pollution

This proposed rule will reduce credible science related to environmental public health, and as a result prolong public exposure to environmental hazards and increase societal costs from unmitigated harm to the environment and the health of our population. I respectfully urge you to withdraw this rule.

Sincerely,

John Wiesman, DrPH, MPH
Secretary of Health